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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,151

12/02/2003

David K. Swanson

03-0515 (US01)

5305

23410

7590

03/29/2011

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EXAMINER

ROANE, AARON F

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

03/29/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/727,151	<b>Applicant(s)</b> SWANSON, DAVID K.	
	<b>Examiner</b> AARON ROANE	<b>Art Unit</b> 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14, 17, 19, 20, 32-34, 36-38, 40-42, 48, 50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34, 36, 37, 40-42 and 50 is/are allowed.
- 6) ☒ Claim(s) 14, 17, 19, 20, 32, 33, 38 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/02/2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 17, 19, 20, 32, 33, 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (U.S. Patent 4,144,890) in view of Edwards et al. (U.S. Patent 5,398,683).

Regarding claims 14, 17, 19, 20, 32, 33, 48 and 51, Hess discloses a device comprising: a tissue stimulation element, in the form of a stimulation electrode ("small flat disk electrode", see col. 3:36-52 and figure 7) configured to emit stimulation energy that is applied to tissue, wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion; and an anchor or means for securing (collectively portions defined by 25, 27, 31, 33 and 37 in col. 2:42-55 and figures 1-3 or portions defined by 41-44 in col. 3:9-18 and figures 4-6), associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue and pressing the stimulation element against the tissue, see col. 2:12- col. 3:52 in general. Hess further disclose "[o]ne type of electrode which may be used is formed by allowing half turns of the helically-coiled conductor to project through the bottom face of the insulating base as illustrated at 53 in FIG. 7. In some cases, a small flat disk electrode

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resting against the tissue to be stimulated may also be entirely sufficient,” see col. 3:36-52 and figure 7. Hess is silent as to the diameter of the “small flat disk electrode.”

Although Hess discloses a first stimulation element, Hess fails to disclose a second stimulation element. **Additionally, Hess fails to disclose the first and second**

**stimulation elements are located on opposite sides of a central portion of the anchor or means for securing the surgical apparatus to the tissue.** Edwards et al. disclose a

medical catheter device and teach providing the catheter with “two pacing electrodes 75 are 0.035” platinum dot electrodes, and are positioned substantially diametrically

opposite each other” (0.035” is 0.889 mm) in order to provide pacing/stimulating electrical energy to tissue, see col. 8:21-25 and figure 8. It is extremely well known in

the electrosurgical/electrotherapeutic art alternate use of a monopolar electrode

configuration and a configuration of bipolar electrodes. Some of the extremely well

known advantages of the configuration of bipolar electrodes over that of the monopolar

electrode configuration are a) limitation of energy conduction to a more defined and

smaller area, b) less wasted energy and c) no need for external return electrode pads.

**Regarding the failure to disclose the first and second stimulation elements are**

**located on opposite sides of a central portion of the anchor or means for securing**

**the surgical apparatus to the tissue, it would have been obvious to one having**

**ordinary skill in the art at the time the invention was made to arrange the bipolar**

**electrodes in configurations with respect to the anchor or means for securing which**

**satisfy the recited first and second stimulation elements are located on opposite sides**

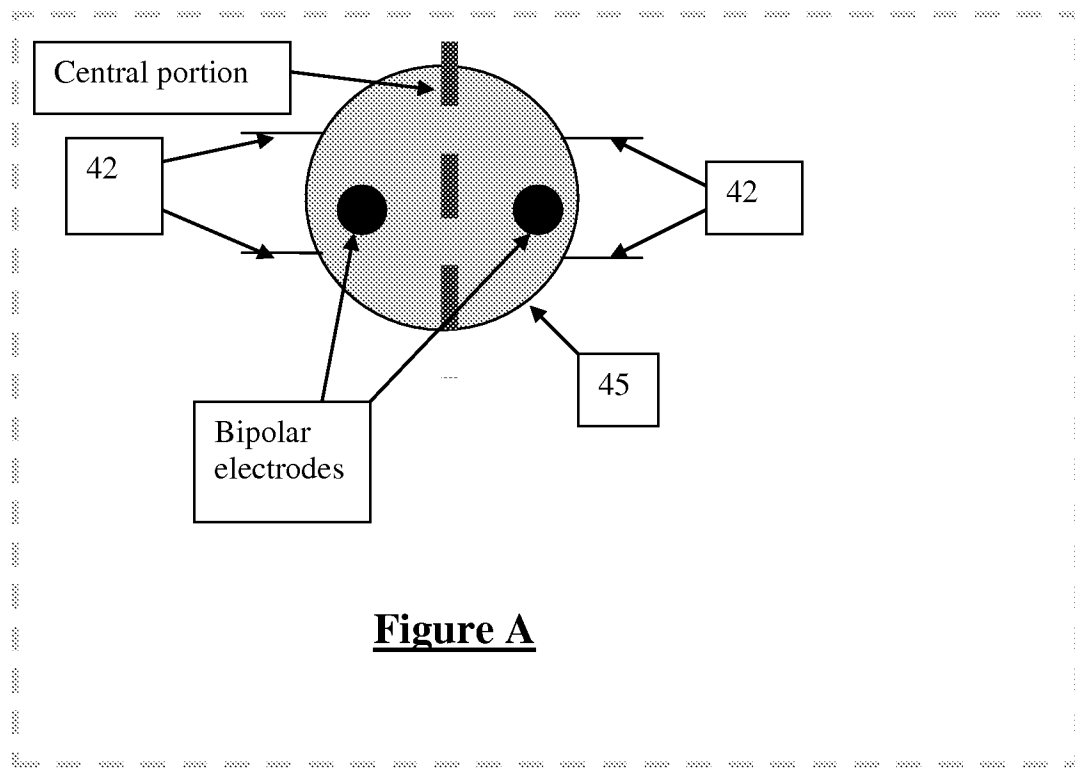
**of a central portion of the anchor or means for securing the surgical apparatus to**

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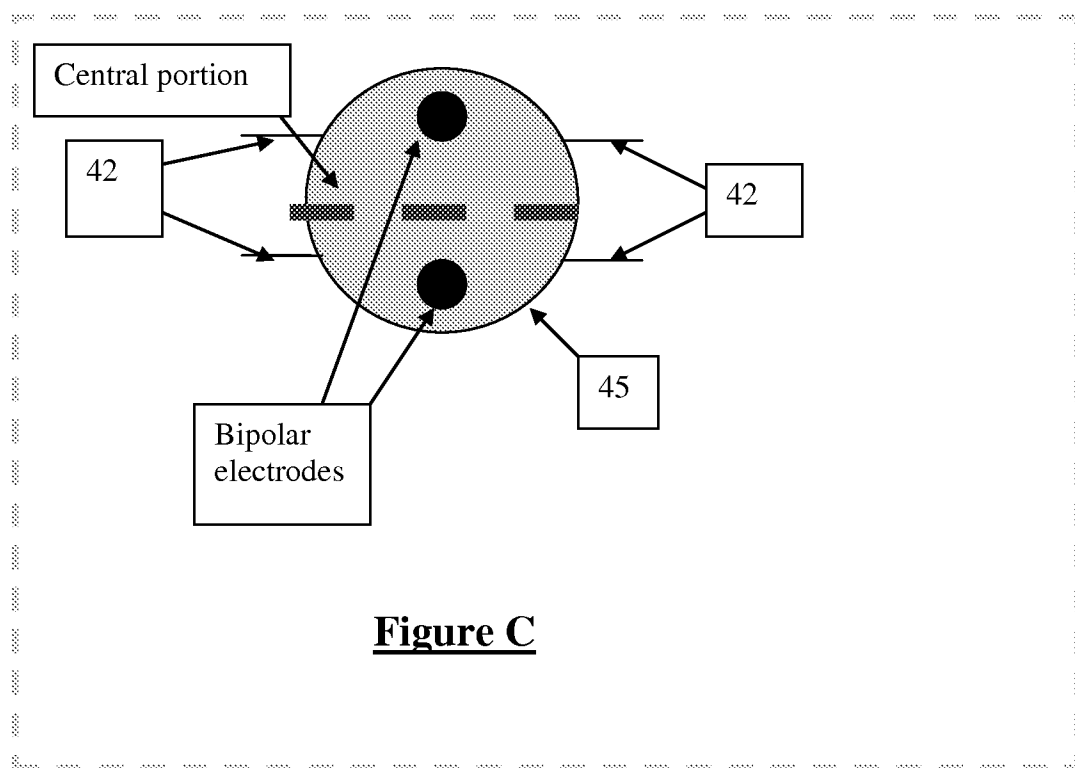
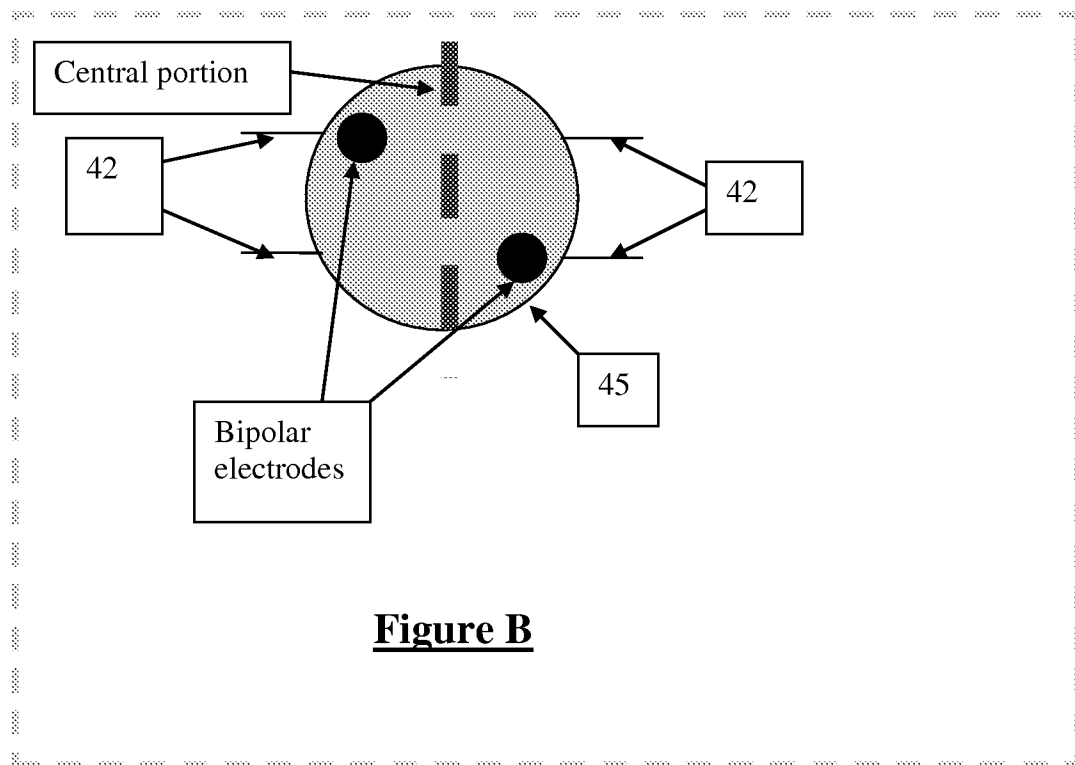
**the tissue (see figures A-C below), since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.**

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Hess, as taught by Edwards et al., to use two small disk like electrode of about 0.889 mm in size that are positioned diametrically opposite each other on the device in order to provide pacing/stimulating electrical energy to tissue, and further as is extremely well known in the art, to provide the device with relatively closely spaced first and second stimulation elements/electrodes in order to provide advantages over the monopolar configuration, the advantages being a) limitation of energy conduction to a more defined and smaller area, b) less wasted energy and c) no need for external return electrode pads, and to arrange the first and second stimulation elements on opposite sides of a central portion of the anchor or means for securing as one of many alternate/equivalent embodiments.

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### **Allowable Subject Matter**

Claims 34, 36, 37, 40-42 and 50 are allowed.

### **Reasons for Allowance**

The following is an examiner's statement of reasons for allowance: the prior art and more specifically the combination of the prior art does provide a properly motivated combination thereof disclosing, implying, suggesting and/or teaching the invention as defined by claim 34, namely the surgical apparatus with particular attention given to a flexible carrier on which a first and second stimulation electrode are located at opposite ends wherein 1) the flexible carrier has a curved unstressed state where the curved interior of the flexible carrier has a highly curved state and 2) the flexible carrier has a reduced curved stressed state where the curved interior of the flexible carrier has a lower curved state.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."



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### **Response to Arguments**

Applicant's arguments with respect to claims 14, 17, 19, 20, 32, 33, 38 and 51 have been considered but are moot in view of the new ground(s) of rejection.

**The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.**

**Due to the new grounds of rejection, this action is made non final.**

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/  
Examiner, Art Unit 3769

/Henry M. Johnson, III/  
Supervisory Patent Examiner, Art Unit  
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